UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,711	10/30/2003	Brieanna Herrick	2864.HERR.PT	8362

26986 7590 08/09/2006

MORRISS O'BRYANT COMPAGNI, P.C.
136 SOUTH MAIN STREET
SUITE 700
SALT LAKE CITY, UT 84101

EXAMINER	
LOPEZ, AMADEUS SEBASTIAN	
ART UNIT	**PAPER NUMBER**
3743	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,711	HERRICK ET AL.	
	Examiner	Art Unit	
	Amadeus S. Lopez	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2/2/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The examiner has considered all references disclosed in the information disclosure statement filed on 02/02/04.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cheek pads in combination with the endotracheal tube holder device must be shown or the feature(s) canceled from the claim(s). Although the detailed drawing of the cheek pad is shown in figures 8A and 8B, it is still required to show it in combination with the overall device. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. Figure 2C is objected to because the figure does not contain any reference numerals which makes it difficult for one to distinguish the parts of the device that are being shown in the particular drawing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 70. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 72. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The abstract of the disclosure is objected to because 1) in line 4, the word ... "an" ... should be deleted and replaced with -- a --; 2) The sentence beginning at line 7 with the words ... "a bite block"... does not follow proper sentence structure, and is currently a run-on sentence. Please restructure this statement. Correction is required. See MPEP § 608.01(b).

7. The disclosure is objected to because of the following informalities:

a. In paragraph 5 in line 5, the word ... "others"... should be deleted and replaced with -- other --.

b. In paragraph 15 in line 3, the word -- to – should be placed before the phrase "... a patient's mouth" forming the phrase -- ... to a patient's mouth --.

c. In paragraph 69 in line 13, the word -- is – should be placed before the word ... "important"... forming the phrase -- This is important --.

d. In paragraph 70 in line 2, the word "is" should be deleted and replaced with -- it --.

e. In paragraph 75, in line10 the words ... "The four"... should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 8,18, and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. **Claims 8 and 18** contain the trademark/trade name VELCRO. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a hook and loop fastening system and, accordingly, the identification/description is indefinite.

10. **Regarding claims 8 and 18**, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

11. **With regards to claim 18,** the claim recites the limitation "the method" as defined in claim 10 when claim 10 is an apparatus claim.

12. **With regards to claim 19,** the claims recites the limitation "the method" as defined in claim 12 when claim 12 is in fact an apparatus claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 7, 8, 12, 13, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5009227 to Nieuwstad.

14. **With regards to claim 1**, what is taught and shown by Nieuwstad in Figs. 1-2 is an endotracheal tube holder for neo-natal use, said endotracheal tube holder comprising: an arcuate face plate (12 and 13) which is disposed adjacent to and in front of a patient's mouth, wherein the face plate includes a receptacle (17) disposed so as to be relatively centered in front of a patient's mouth, and wherein the face plate has a first attaching arm (left wing of face plate) and a second attaching arm (right wing of face plate) which are contiguous with a patient's cheeks (see. Fig. 1) as they extend from either side of the face plate towards a back of a patient's head; an endotracheal tube holder member (11) disposed in front of the arcuate faceplate, and which is configured for positioning an endotracheal tube away from a patient's palate; a bite block (19) disposed so as to be held by the endotracheal tube holder member, and which extends

inwards into the patient's mouth, wherein the bite block is surrounded by a rubber sleeve (20) so as to cushion the gums and teeth as they are pressed against the bite block (Col. 3, line 63 to column 4, line 4); and a plurality of non-elastic attachment straps (25 and 26; Fig. 1) which are coupled to the first and the second attaching arms of the face plate, and which extend around the neo-natal patient's head so as to secure the face plate in front of the patient's mouth.

15. **With regards to claim 7,** what is taught and shown by Nieuwstad in figures 1-2 is an endotracheal tube holder wherein the endotracheal tube holder member further comprises: a first cheek pad disposed between the first attaching arm and the patient's cheek; and a second cheek pad disposed between the second attaching arm and the patient's cheek, to thereby cushion the patient's cheek from the first and the second attaching arms (Col. 2, lines 8-13).

16. **With regards to claim 8**, what is taught and shown by Nieuwstad in figures 1-2 is an endotracheal tube holder wherein the plurality of non-elastic attachment straps (25 and 26) are coupled to the first and the second attaching arms using a hook and loop fastening system, to thereby enable easy and rapid adjustments thereof (Col. 3, lines 30-40).

17. **With regards to claim 12**, what is taught and shown by Nieuwstad in figures 1-2, is an endotracheal tube holder wherein the faceplate is constructed of a clear polycarbonate material to thereby assist in visual inspection of the patient (Col. 3, lines 15-20).

18. **With regards to claim 13**, what is taught and shown by Nieuwstad in figures 1-2 is a method for providing an endotracheal tube holder for neo-natal use to thereby avoid damaging tissues and bones of the neo-natal patient, said method comprising the steps of: (1) providing the endotracheal tube holder including an arcuate face plate (12 and 13), a receptacle (17) centered thereon, a first attaching arm and a second attaching arm (left and right wings of face plate), a tube holder member (11) which is configured for holding an endotracheal tube and disposed within the receptacle, a plurality of attachment straps (25 and 26; Fig. 1) which are coupled to the first and the second attaching arms of the face plate, and which extend around the neo-natal patient's head so as to secure the face plate in front of the patient's mouth; (2) centering the tube holder member in front of the patient's mouth (Fig. 1); (3) providing a bite block (19) as part of the tube holder member which extends inwards into the patient's mouth, wherein the bite block is surrounded by a rubber sleeve (20) which functions so as to cushion the gums and teeth as they are pressed against the bite block (Col. 3, line 63 to column 4, line 4), and wherein an endotracheal tube passes through the tube holder member so as not to make contact with the patient's gums or teeth; and (4) constructing the plurality of attachment straps using a non-elastic material to thereby avoid creating pressure on the neo-natal patient's cranial structure (Col. 2, lines 12-16).

19. **With regards to claim 18**, what is taught and shown by Nieuwstad in figures 1-2 is wherein the method further comprises the step of providing the hook and loop fastening system on the plurality of attachment straps (25 and 26) to thereby enable quick and easy adjustments to the endotracheal tube holder (Col. 3, lines 30-40).

20. **With regards to claim 20**, what is taught and shown is the method for protecting gums, teeth, and palate of a neo-natal patient when using an endotracheal tube holder, said method comprising the steps of: (1) providing the endotracheal tube holder including an arcuate face plate (12 and 13), a receptacle (17) centered thereon, a first attaching arm and a second attaching arm (left and right wings of face plate), an endotracheal tube holder member which is configured for holding an endotracheal tube and disposed within the receptacle, a plurality of attachment straps (25 and 26) which are coupled to the first and the second attaching arms of the face plate, and which extend around the neo-natal patient's head so s to secure the face plate in front of the patient's mouth; and (2) disposing a cushioned bite block (19) on the tube holder member, enabling the bite block to extend into the patient's mouth a provide a surface for the gums and teeth to rest without causing damage thereto, wherein the endotracheal tube passes through the cushioned bite block so as not to touch the gums and teeth, and wherein the cushioned bite block centers the endotracheal tube in the neo-natal patient's mouth to thereby prevent injury to a palate therein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

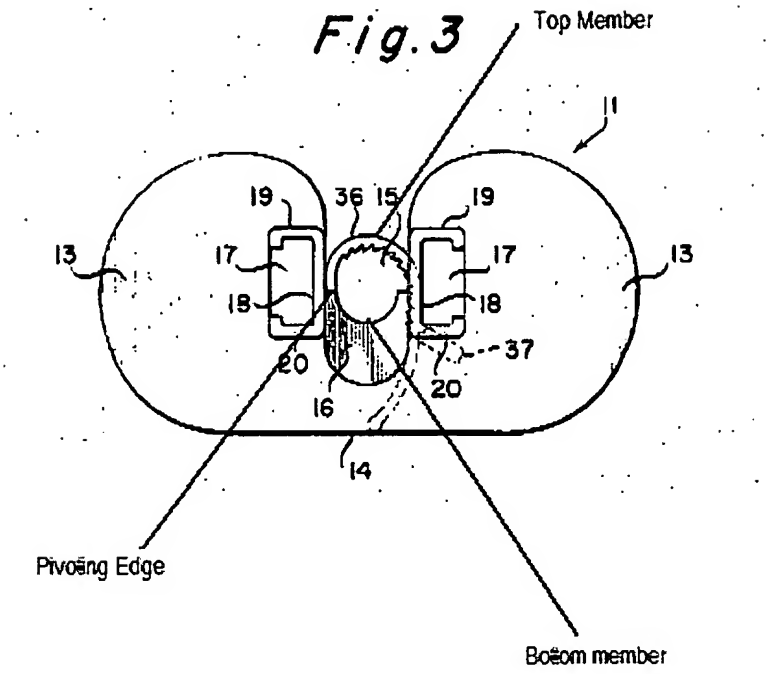
21. **Claims 1-6, 8-9, 11-12, and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 3774616 to White et al in view of Nieuwstad.**

22. With regards to claim 1, what is taught and shown by White et al in Figs. 1-3 is an endotracheal tube holder for neo-natal use, said endotracheal tube holder comprising: an arcuate face plate (13) which is disposed adjacent to and in front of a patient's mouth, wherein the face plate includes a receptacle (15) disposed so as to be relatively centered in front of a patient's mouth, and wherein the face plate has a first attaching arm (left wing of face plate) and a second attaching arm (right wing of face plate) which are contiguous with a patient's cheeks (see. Fig. 1) as they extend from either side of the face plate towards a back of a patient's head; an endotracheal tube holder member (36) disposed in front of the arcuate faceplate, and which is configured for positioning an endotracheal tube away from a patient's palate; a bite block (formed by pieces 18, 19, and 20) disposed so as to be held by the endotracheal tube holder member, and which extends inwards into the patient's mouth, wherein the bite block is surrounded by a rubber sleeve (Col. 4, line 59 to Col. 5, line 1) so as to cushion the

provide cushion for the teeth and gums of a user); and a plurality of attachment straps (22) which are coupled to the first and the second attaching arms of the face plate, and which extend around the neo-natal patient's head so as to secure the face plate in front of the patient's mouth. What is not taught by White et al is that the bite block is disposed so as to be held by the endotracheal tube holder member. After reviewing the specification, the examiner has concluded that the applicant never establishes any criticality to have the bite block disposed on the endotracheal tube holder member. Therefore it would have been an obvious matter of design choice to have the bite block disposed to be held by the endotracheal tube holder member or the face plate as taught by White et al because both are effective locations for the bite block to originate from allow the user to bite down on. Further what is not taught by White et al is that the bite block has a rubber sleeve placed over it to provide cushioning for the gums. What is taught by White et al is the bite block in the form of rubber tubes that would provide the same cushioning as a rubber sleeve. Therefore it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to either utilize a rubber tube or a separate rubber sleeve to act as a bite block cushioning for a user's mouth because both will provide a comfortable bite block for the user. Further what is not taught by White et al is that attachment straps (22) are non-elastic. What is taught and shown by Nieuwstad in Figures 1-2 is an endotracheal tube holder that utilizes non-elastic head straps (25 and 26; Col 2, lines 12-16). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the attachment straps taught by White et al to be non-elastic as taught by

Nieuwstad because as taught by Nieuwstad because an elastic headband would prevent the "necessary free expansion and contraction of the cranial bones."

23. **With regards to claim 2**, what is taught and shown by White et al in figures 1-3 and the figure below is an endotracheal tube holder wherein the endotracheal tube holder member further comprises: a bottom member generally formed as half a cylinder cut lengthwise (16; Fig. 3) which includes a first semicircular depression along a long axis for receiving the endotracheal tube; and a top member (formed by piece 36; Fig. 3) generally formed as half a cylinder cut lengthwise, which includes a second semicircular depression for receiving the endotracheal tube, wherein the bottom member is coupled to the top member along a pivoting edge (labeled below) which is parallel to the lengthwise axis, such that the bottom member and the top member form a cylinder with a hole (15) formed from the first and second semicircular depressions through the center thereof.



24. **With regards to claim 3**, what is taught and shown by White et al in figures 1-3 is an endotracheal tube holder wherein the endotracheal tube holder member further comprises a bore hole (17) parallel to the lengthwise axis, such that a second tube can be inserted through the bore hole (See Fig. 1), to thereby introduce fluids into the patient at the same time that the endotracheal tube is being utilized. After reviewing the specification, the examiner has concluded that the applicant never establishes any criticality for having a bore hole through the top member. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the bore hole located anywhere on the endotracheal tube holder device that would allow a second tube to be inserted to provide a feed tube to the user.

25. **With regards to claim 4**, what is taught and shown by White et al in figures 1-3 is an endotracheal tube holder wherein the endotracheal tube holder member further comprises a bore hole (17) through the faceplate (13) so as to be parallel to the lengthwise axis, such that a second tube (39) can be inserted through the bore hole, to thereby introduce fluids into the patient at the same time that the endotracheal tube is being utilized. What is not taught by White et al is the bore hole is through the bottom member. After reviewing the specification, the examiner has concluded that the applicant never establishes any criticality for having the bore hole through the bottom member. Therefore it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to have the bore hole disposed anywhere on the endotracheal tube holder apparatus that would allow a second tube to be inserted through.

26. **With regards to claim 5**, what is taught and shown by White et al in figures 1-3 is an endotracheal tube holder with all the limitations of claim 5 with the exception of wherein the endotracheal tube holder member further comprises the bite block which is formed from the top member and the bottom member, and which extends inwards into the patient's mouth. What is taught by White et al is a bite block (formed by pieces 18, 19, and 20) disposed so as to be held by the face plate (13), and which extends inwards into the patient's mouth. What White et al does not teach is that the bite block is disposed so as to be held by the endotracheal tube holder member. After reviewing the specification, the examiner has concluded that the applicant never establishes any criticality to have the bite block disposed on the endotracheal tube holder member.

Therefore it would have been an obvious matter of design choice to have the bite block disposed to be held by the endotracheal tube holder member or the face plate as taught by White et al because both are effective locations for the bite block to originate from and provides an area in which the user can bite down on.

27. **With regards to claim 6**, what is taught and shown by White et al in figures 1-3 is an endotracheal tube holder wherein the endotracheal tube holder member further comprises: the top member having a ratcheting hook (37); and a member (36) having a plurality of complementary receiving indentations (Col. 3, line 60 to Col. 4, line 15) against which the ratcheting hook is able to grip, thereby enabling the top member and the bottom member to hold endotracheal tubes of varying diameters within the first and the second semicircular depressions in accordance with how far the ratcheting hook is pressed into the receiving indentations (Fig. 3; the serrated edge of strap 36 can be adjusted so that tooth 37 engages one of the indentations on strap 36 so varying diameters of endotracheal tubes can fit within the passage formed (15). After reviewing the specification the examiner has concluded that the applicant never discloses any criticality for having the complementary indentations on the bottom member and the ratchet hook as the top member. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the complementary indentations and ratchet disposed in any configuration that would allow the diameter size of the receptacle to be adjusted for the accommodation of different sized endotracheal tubes.

28. **With regards to claim 8**, what is taught and shown by White et al is an endotracheal tube holder with all the limitations of claim 8 with the exception of wherein the plurality of non-elastic attachment straps are coupled to the first and second attaching arms using a hook and loop fastening system. What is taught and shown by Nieuwstad in figures 1-2 is an endotracheal tube holder wherein the plurality of non-elastic attachment straps (25 and 26) are coupled to the first and the second attaching arms using a hook and loop fastening system, to thereby enable easy and rapid adjustments thereof (Col. 3, lines 30-40). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the attachment straps taught by White et al to utilize a hook and loop fastening system because it is well known in the art to be an effective means to fasten a breathing device to the head of a user.

29. **With regards to claims 9 and 11**, what is taught and shown by White et al in figures is an endotracheal tube holder with all the limitations of claim 9 with the exception of wherein the plurality of non-elastic attachment straps (22) further comprises: a first strap which is coupled to the first and the second attaching arms, and which extends around a base of a neck of the patient; a second strap which is coupled to the first attaching arm, extends upwards in a curve along the patient's cheek to a patient's forehead, and then back down the patient's other cheek where it is coupled to the second attaching arm; a third and fourth strap which are coupled to the first strap at the base of the neck, and which extend forward over the head so as to be coupled to the second strap at approximately the patient's forehead; and a fifth strap which is

coupled to the second strap generally above the patient's eyes and in generally horizontal position. What is taught and shown by Nieuwstad in figures 1-2 is an endotracheal tube holder that utilizes a plurality of straps to attach the endotracheal tube holder to the head of the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the attachment straps of White et al with that taught by Nieuwstad because it is well known in the art and obvious that the more straps that are used to attach the endotracheal tube holder to the user would provide more support. Therefore more strapping is a mere duplication of parts with the intention of providing increased support with each added strap.

30. **With regards to claim 12**, what is taught and shown by in White et al in figures 1-3, is an endotracheal tube holder with all the limitations of claim 12 with the exception of wherein the faceplate is constructed of a clear polycarbonate material to thereby assist in visual inspection of the patient. What is taught and shown by Nieuwstad is an endotracheal tube holder wherein the faceplate is constructed of a clear polycarbonate material to thereby assist in visual inspection of the patient (Col. 3, lines 15-20). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the faceplate as taught by White et al to be made of a clear polycarbonate material for "easy visual monitoring of the endotracheal tube positioning," as taught by Nieuwstad

31. **With regards to claim 13,** , what is taught and shown by White et al is the method for providing an endotracheal tube holder for neo-natal use to thereby avoid damaging tissues and bones of the neo-natal patient, said method comprising the steps

of: (1) providing the endotracheal tube holder including an arcuate face plate (13), a receptacle (15) centered thereon, a first attaching arm and a second attaching arm (left and right wings of face plate), a tube holder member (36) which is configured for holding an endotracheal tube and disposed within the receptacle, a plurality of attachment straps (25 and 26; Fig. 1) which are coupled to the first and the second attaching arms of the face plate, and which extend around the neo-natal patient's head so as to secure the face plate in front of the patient's mouth; (2) centering the tube holder member in front of the patient's mouth (Fig. 1); (3) providing a bite block (formed by pieces 18, 19, and 20) as part of the tube holder member which extends inwards into the patient's mouth, and wherein an endotracheal tube passes through the tube holder member so as not to make contact with the patient's gums or teeth; What is not taught by White et al is wherein the bite block is surrounded by a rubber sleeve which functions so as to cushion the gums and teeth as they are pressed against the bite block; and (4) constructing the plurality of attachment straps using a non-elastic material to thereby avoid creating pressure on the neo-natal patient's cranial structure. What is taught by White et al is the bite block in the form of rubber tubes that would provide the same cushioning as a rubber sleeve. Since the applicant never establishes any criticality as to why a rubber sleeve would be more effective than just having the tubes made of rubber acting as a bite block, it therefore would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to either utilize a rubber tube or a separate rubber sleeve to act as a bite block cushioning for a user's mouth because both will provide a comfortable bite block for the user. What is

taught and shown by Nieuwstad in Figures 1-2 is an endotracheal tube holder that utilizes non-elastic head straps (25 and 26; Col 2, lines 12-16). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the attachment straps taught by White et al to be non-elastic as taught by Nieuwstad because as taught by Nieuwstad because an elastic headband would prevent the "necessary free expansion and contraction of the cranial bones."

32. **With regards to claim 14**, what is taught and shown by White et al in figures 1-3 is the method wherein the method comprises the steps of: (1) forming a bottom member as half a cylinder cut lengthwise (16; Fig. 3), which includes a semicircular depression along a long axis for receiving the endotracheal tube; and (2) forming a top member generally as half a cylinder cut lengthwise (formed by piece 36; Fig. 3), which includes a semicircular depression for receiving the endotracheal tube, wherein the bottom member is coupled to the top member along a pivoting edge (labeled in fig. Above) which is parallel to the lengthwise axis, such that the bottom member and the top member form a cylinder with a hole (15) formed from the semicircular depressions through the center thereof; and (3) boring a hole (17) parallel to the lengthwise axis through the top member to thereby enable a second tube to be inserted into the patient's mouth at the same time as an endotracheal tube.

33. **With regards to claim 15,** what is taught and shown by White et al in figures 1-3 is an endotracheal tube holder with all the limitations of claim 5 with the exception of wherein the endotracheal tube holder member further comprises the bite block which is formed from the top member and the bottom member, and which extends inwards into

the patient's mouth. What is taught by White et al is a bite block (formed by pieces 18, 19, and 20) disposed so as to be held by the face plate (13), and which extends inwards into the patient's mouth. What White et al does not teach is that the bite block extends from the top and bottom member. After reviewing the specification, the examiner has concluded that the applicant never establishes any criticality to have the bite block disposed on the endotracheal tube holder member so that it extends from the top and bottom member. Therefore it would have been an obvious matter of design choice to have the bite block disposed to be held by the endotracheal tube holder member or the face plate as taught by White et al because both are effective locations for the bite block to originate from and provide an area that allows the user to bite down on.

34. **With regards to claim 16,** what is taught and shown by White et al in figures 1-3 is the method further comprising the steps of: (1) providing a ratcheting hook on the lower member; and (2) providing a plurality of complementary receiving indentations against which the ratcheting hook is able to grip, thereby enabling the top member and the bottom member to hold endotracheal tubes of varying diameters within the semicircular depressions in accordance with how far the ratcheting hook is pressed into the receiving indentations. After reviewing the specification the examiner has concluded that the applicant never discloses any criticality for having the complementary indentations on the bottom member and the ratchet hook as the top member. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the complementary indentations and ratchet

disposed in any configuration that would allow the diameter size of the receptacle to be adjusted for the accommodation of different sized endotracheal tubes.

35. **With regards to claim 17**, what is taught and shown by White et al in figures 1-3 is the method with all the limitations of claim 17 with the exception of the method further comprising the steps of: (1) providing a first cheek pad disposed between the first attaching arm and the patient's cheek; and (2) providing a second cheek pad disposed between the second attaching arm and the patient's cheek, to thereby cushion the patient's cheek from the first and second attaching arms. What is taught and shown by Nieuwstad in figures 1-2 is an endotracheal tube holder wherein the endotracheal tube holder member further comprises: a first cheek pad disposed between the first attaching arm and the patient's cheek; and a second cheek pad disposed between the second attaching arm and the patient's cheek, to thereby cushion the patient's cheek from the first and the second attaching arms (Col. 2, lines 8-13). Therefore it would have been obvious to one of ordinary skill at the time the invention was made to modify the endotracheal tube holder attachment straps to include cheek pads to prevent skin irritation from the friction of the straps against the skin when the user moves.

36. **With regards to claim 18,** what is taught and shown by White et al is a method with the exception of wherein the method further comprises the step of providing the hook and loop fastening system of a hook and loop fastening system on the plurality of attachment straps. What is taught and shown by Nieuwstad in figures 1-2 is an endotracheal tube holder wherein the plurality of non-elastic attachment straps (25 and 26) are coupled to the first and the second attaching arms using a hook and loop

fastening system, to thereby enable easy and rapid adjustments thereof (Col. 3, lines 30-40). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the attachment straps taught by White et al to utilize a hook and loop fastening system because it is well known in the art to be an effective means to fasten a breathing device to the head of a user.

37. **With regards to claim 19,** what is taught and shown by White et al is a method with all the limitations of claim 19 with the exception of wherein the method further comprises the step of constructing the endotracheal tube holder of a clear polycarbonate material to thereby assist in visual inspection of the patient. What is taught and shown by Nieuwstad is an endotracheal tube holder wherein the faceplate is constructed of a clear polycarbonate material to thereby assist in visual inspection of the patient (Col. 3, lines 15-20). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the faceplate as taught by White et al to be made of a clear polycarbonate material for "easy visual monitoring of the endotracheal tube positioning," as taught by Nieuwstad.

38. Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al as applied to claim 1 above, and further in view of US Patent No. 6067985 to Islava.

39. With regards to claim 7, what is taught and shown by White et al in figures 1-3 is an endotracheal tube holder with all the limitations of claim 7 with the exception of wherein the endotracheal tube holder member further comprises: a first cheek pad disposed between the first attaching arm and the patient's cheek; and a second cheek

disposed between the second attaching arm and the patient's cheek, to thereby cushion the patient's cheek from the first and the second attaching arms. What is taught and shown by Islava in Fig 3 is an endotracheal tube holder member that further comprises a first cheek pad (124) disposed between the first attaching arm and the patient's cheek; and a second cheek pad (124) disposed between the second attaching arm and the patient's cheek, to thereby cushion the patient's cheek from the first and the second attaching arms. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the first and second attaching arms of White et al. to include cheek pads as taught by Islava to prevent skin irritation to the user and make it more comfortable to wear.

40. With regards to claim 17, what is taught and shown by White et al is the method for providing an endotracheal tube holder for neo-natal use to thereby avoid damaging tissues and bones of the neo-natal patient with the exception of the method further comprising the steps of: (1) providing a first cheek pad disposed between the first attaching arm and the patient's cheek; and (2) providing a second cheek pad disposed between the second attaching arm and the patient's cheek, to thereby cushion the patient's cheek from the first and the second attaching arms. What is taught and shown by Islava in Fig 3 is an endotracheal tube holder member that further comprises a first cheek pad (124) disposed between the first attaching arm and the patient's cheek; and a second cheek pad (124) disposed between the second attaching arm and the patient's cheek, to thereby cushion the patient's cheek from the first and the second attaching arms. Therefore it would have been obvious to one of ordinary skill in the art

at the time the invention was made to modify the first and second attaching arms of White et al. to include cheek pads as taught by Islava to prevent skin irritation to the user and make it more comfortable to wear.

41. **Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over White et al in view of Nieuwstad in further view of US Patent No. 5406340 to Hoff.** What is taught and shown by White et al in view of Nieuwstad is the endotracheal tube holder with all the limitations of claim 10 with the exception of wherein the plurality of attachment straps further comprises an eye covering which is disposed across the patient's eyes, and which has a strap threaded through the eye covering on either side of the patient's eyes. What is taught and shown by Hoff in figure 3 is protective eye covering in which a strap is threaded through the eye covering on either side of the patient's eyes. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the plurality of straps taught by White et al/Nieuwstad to include a eye covering for the purpose of providing protection from light waves that could be harmful to the eyes of a user or to protect them from small particles touching the surface of the eye. It is well known in the art to utilize strapping means to fix a protective eye covering on the head of a user. Further, what is taught and shown by Nieuwstad in figures 1-2 is an endotracheal tube holder that utilizes a plurality of straps to attach the endotracheal tube holder to the head of the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the attachment straps of White et al with that taught by Nieuwstad because it is well known in the art and obvious that the more straps that are used to attach the

endotracheal tube holder to the user would provide more support. Therefore more strapping is a mere duplication of parts with the intention of providing increased support

Conclusion

42. The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure. US 5305742, US 4832019, US 5345931, US 5513633, US 6533761, US 5509409, US 5894840, US 4270529, US 4744358, US 4502476, and US 5069206.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amadeus S Lopez
Examiner
Art Unit 3743
August 2, 2006

ASL

Henry Bennett
Supervisory Patent Examiner
Group 3700